Johnson & Johnson

BABY PRODUCTS COMPANY

STRICTLY CONFIDENTIAL

March 3, 1975

SUBJECT: Management Authorization for Additional Talc Safety Studies

Dr. D.R. Petterson

This memo is to request authorization from the Management Board of $90,000 to cover additional recommended safety studies for talc. This is money not present in the current R&D budget.

Our current posture with respect to sponsorship of talc safety studies has been to initiate studies only as dictated by confrontation. This philosophy, so far, has allowed us to neutralize or hold in check data already generated by investigators who question the safety of talc. The principal advantage for this operating philosophy lies in the fact that we minimize the risk of possible self-generation of scientific data which may be politically or scientifically embarrassing. It has been reasoned that we should wait until an issue is raised before we move towards conducting temporizing studies of our own. The studies proposed under existing philosophy correspond to a budgetary amount of $60,000 (A and C in appendix).

However, this approach leaves the talc franchise and the company image open to repeated erosion by prior public disclosure of suspected hazards and adversary politicking. Also, there exists a danger that the latent period for generating J&J data might be too great for the data to be effective. It has come to our attention that Drs. Fine and Peters of the Harvard School of Public Health will be presenting to the meeting of the American Occupational Medical Association in April, 1975 a paper entitled "Respiratory Morbidity in Talc Workers". This study will show an increase in respiratory morbidity amongst rubber tire workers exposed to talc dust in the factory. NIOSH is also committed to do both an epidemiology and pulmonary function study of miners in the talc mines of Vermont.

Plaintiff's Exhibit 2514

Initial pulmonary data will be obtained within the next two months.

An alternative philosophy has been presented in recent discussions at the Talc Advisory Group which would favor us assuming a more anticipative approach. We would carry out other reasonable safety studies to continue our contradiction of generated negative data and to anticipate questions on safety which will probably be raised. This philosophy offers maximal leverage for defending the product and is consistent with the policy practised with regards to clearance of a new product. However, it faces the risk of revealing marginal data which may be difficult to deal with politically and/or scientifically. In spite of this risk, we believe that the potential benefits far outweigh the risks, and provide for a more solid scientific base for baby powder. Following this alternative posture will necessitate an additional expenditure of $30,000 for a Neutron Activation Study in Hamsters (B in appendix) thus totaling $90,000.

Details of the three studies are described in attachment A.

Study A is a prospective study on Italian Talc Millers proposed by Professor Rubino and directed towards demonstrating that pulmonary function is not impaired by exposure to cosmetic grade talc.

Study B is a Neutron Activation Study in Hamsters to be performed by Battelle which would render quantitative lung clearance and deposition data in relationship to baby exposure.

Study C covers funds to allow Johnson & Johnson's monitoring of the NIOSH Harvard Study of Vermont Talc Workers and would be directed toward analytical and statistical verification of the data to be gathered by the Harvard investigators.

G. Lee

paj

cc: Dr. B. Semple